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| | APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
|--|--|----------------|----------------------|-------------------------|------------------|--|--|
| | 10/018,807 04/17/2002 | | Toshiaki Kumazawa | 2994.1 | 2129 | | |
| | 5514 75 | 590 08/04/2006 | | EXAM | EXAMINER | | |
| | FITZPATRICK CELLA HARPER & SCINTO | | | CEPERLEY, MARY | | | |
| | 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 | | | ART UNIT | PAPER NUMBER | | |
| | | | | 1641 | | | |
| | | | | DATE MAILED: 08/04/2006 | 6 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application | Application No. Applicant(s) | | | | | | | |
|--|--|-------------|--|-----------------|--------|--|--|--|--|--|
| | | | . 77 | KUMAZAWA ET AL. | | | | | | |
| Office Action Summary | | Examiner | | Art Unit | | | | | | |
| 0 | | Mary (Mol | ly) E. Ceperley | 1641 | | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | | | |
| Status | | | | | | | | | | |
| 2a)☐ This ad 3)☐ Since | Responsive to communication(s) filed on <u>26 May 2006</u> . This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | | |
| Disposition of Claims | | | | | | | | | | |
| 4) ☐ Claim(s) 18-28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 18-28 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement. | | | | | | | | | | |
| Application Papers | | | | | | | | | | |
| 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | | | |
| Priority under 3 | 5 U.S.C. § 119 | | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | | |
| 2) Notice of Draft 3) Information Di | rences Cited (PTO-892) sperson's Patent Drawing Review (PT sclosure Statement(s) (PTO-1449 or P ail Date <u>5[12</u>] 06 and 5[26 | TO/SB/08) | 4) Interview Summary (Paper No(s)/Mail Dat 5) Notice of Informal Pa 6) Other: | te |)-152) | | | | | |

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1) The examiner confirms that the U.S. counterparts of the Japanese applications referred to in the third paragraph of the May 26, 2006 Remarks have been considered.

2) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3) Claims 18, 19 and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al (U.S. 5,187,066).

Becker et al describe a "hydrophobic surface" comprised of a hydrophilic support [corresponding to the "immunoassay carrier" of claim 18 of this application] which has been modified by treatment with a "hydrophobic reagent" {col. 6, lines 34-39}. The hydrophobic reagents include alkoxysilanes {col. 6, lines 64-66; col. 7, lines 3-5; col. 8, lines 16-19} which are the same as the compounds of Formula (I) of claim 18 of this application. After the formation of the combination of the hydrophilic solid support modified to have a hydrophobic surface, the Becker et al surface is incubated with an antigen to attach the antigen to the surface {col. 9, lines 9-14}; the antigen may be pretreated with a "solubilizing agent" {col. 7, lines 46-66} which corresponds to the "surfactant" of claim 18 of this application {col. 6, lines 3-27}. The "solid phase" of claim 18 of this application is the same as, and therefore is anticipated by, the Becker et al composition comprised of a "hydrophobic surface" ["an immunoassay carrier coated with a hydrophobic silicon compound"] containing a solubilized antigen ["surfactant" and "immobilized" "immunoreactive substance"].

For the alkyltrialkoxysilane of claim 19, see Becker et al at col. 7, lines 4 and 5: "octyltriethoxysilane".

Fort the glass and ceramic supports of claim 21, see Becker et al at col. 5, line 60.

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For the porous support of claim 23, see Becker et al at col. 5, lines 36-37.

For the glass fiber membranes of claims 22 and 24, see Becker et al at col. 5, lines 65-66.

For the non-ionic surfactants of claims 25-27, see Becker et al at col. 6, lines 3-6 and 23-25.

- **4)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5) Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over a) Becker et al (U.S. 5,187,066) taken in combination with each of b) Kiaei et al (U.S. 5,639,626) or Chu (U.S. 6,284,194).

Becker et al is applied for its description of an immunoassay surface comprised of the components described in paragraph *3)* above.

Kaei et al and Chu describe the use of surfactants of the type described in claims 25-27 of this application as being well known components of immunoassay solid support surfaces. See Chu, col. 7, line 44 – col. 8, line 31 and Kiaei et al, col. 3, lines 57-67.

Given the fact that the use of a surfactant as a component of immunoassay solid support surfaces is well known for the purpose of reducing non-specific binding of proteins {Kiaei et al, col. 4, lines 62-65; Chu, col. 8, lines 35-40; Becker et al, col. 5, lines 53-54}, it would be obvious to substitute the known surfactants used in the immunoassay supports of the Kiaei et al or Chu as equivalent surfactants in the immunoassay supports of Becker et al, as claimed, with the expectation of obtaining similarly useful immunoassay supports [claims 25-27].

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Given the fact that an appropriate "target substance" for immunoassays is well known to include either member of the specific binding pair comprised of an antigen and its corresponding antibody {Becker et al, col. 1, lines 21-41; Kiaei et al, col. 2, lines 49-57; Chu, col. 2, lines 56-59}, it would be obvious to substitute the corresponding antibody as an equivalent target in the immunoassay of Becker et al, as claimed, with the expectation of obtaining a similarly useful assay for detection of the corresponding antigen [claim 28].

6) Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Becker et al (U.S. 5,187,066).

Becker et al is applied for its description of an immunoassay surface comprised of the components described in paragraph *3)* above. Becker et al does not specifically describe the use of "octadecy/triethoxysilane" {claim 20} as a component of the immunoassay surface. However, the Becker et al description of the use of "alkoxysilanes of 4-20 atoms ... for example, "octy/triethoxysilane" is considered to render obvious the use of the homologous {C₈ versus C₁₈} "octadecyltriethoxysilane" compound of claim 20 as a component of an immunoassay surface, as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at

866-217-9197 (toll-free).

August 03, 2006

Mary E. Ceperley
Mary (Molly) E. Ceperley
Primary Examiner
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